

REMARKS

In the Office Action, claims 1-11 are rejected and claims 12-28 are withdrawn from consideration. By this amendment, Applicant has canceled claims 1, 7, and 11 and added new claims 29-30. As a result, claims 2-6, 8-10, and 12-30 are pending. Reconsideration in view of the above amendments and following remarks is respectfully requested.

The above added claims are supported in the specification. With respect to added claim 29, see, e.g., page 4, line 31 – page 5, line 2; page 6, lines 8-13; and Example 3. With respect to claim 30, see, e.g., page 5, line 3 – page 6, line 6.

Applicants respectfully submit that these amendments overcome the objection to claims 1, 7, and 11 and the rejections of claims 1-11 and therefore request reconsideration of the objection and rejections and allowance of claims 2-6, 8-10, and 29-30. These amendments are being made to facilitate rapid allowance of claims to important subject matter. Applicant does not acquiesce in the correctness of the rejections and reserves the right to pursue the full scope of the subject matter of the original claims in a subsequent patent application that claims priority to the instant application.

Objection to Claims 1, 7, and 11

The claims pending in this case, as amended, no longer refer to chemical numbers of compounds, thus obviating this objection.

Rejection of Claims 1, 6, and 8 under 35 USC 102 over Touitou et al.

Touitou et al. purport to disclose transdermal delivery of Delta8-THC. The claims now pending, as amended, recite cannabidiol, not Delta8-THC. Therefore, Touitou et al. do not anticipate the pending claims, as amended.

In order to facilitate allowance of the pending claims, as amended, Applicants add that the subject matter of the claims under consideration, as amended, also was not obvious over Touitou et al. alone or in combination with other cited references. As noted above, putting aside what Touitou et al. actually teach reading the reference in the most favorable light only for purposes of this reply, Touitou et al. teach transdermal delivery of Delta8-THC.

Delta8-THC is chemically different from Cannabidiol ("CBD") and therefore it could not have been obvious that CBD can be delivered transdermally based on transdermal delivery of Delta8-THC.

CBD has the formula: 2-[(1R,6R)-3-methyl-6-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzendiol.

Delta8-THC has the formula: (6AR-trans)-6A,7,10,10A-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo(b,d)pyran-1-ol.

Each molecule has its own chemistry and pharmacologic characteristics that make its transdermal delivery different. In general, molecules can successfully be delivered if they have certain characteristics, e.g., if they are potent, are more lipophilic than hydrophilic, are not too big, are not subject to significant skin metabolism, have a clearance rate from the body that is not too fast, and are not skin irritants or sensitizers. However, in fact, generalizations about classes of drugs are risky because small differences in these properties can make a difference. Small changes in chemistry and pharmacologic response can "make or break" any molecule's

transdermal success rating. Therefore, one could not have predicted with any reasonable degree of success that CBD could be delivered transdermally in a pharmacologically active state.

Note that Touitou et al., at page 10, left column, first full paragraph, state that the authors chose to use Delta8-THC rather than Delta9-THC for several reasons, including:

"The latter is quite unstable, giving the inactive cannabinol on oxidation. In transdermal administration, which by its very nature takes place over relatively long periods of time, oxidation processes have to be taken into account."

Note that the structure of Delta9-THC, which has the formula: (6AR-trans)-6A,7,8,10A-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo(b,d)pyran-1-ol, is much more similar to the structure of Delta 8-THC than is the structure of CBD. Yet, even between compounds as structurally similar as Delta8-THC and Delta9-THC, predictions cannot be made, as is made clear by Touitou et al.

Therefore, the subject matter of the claims under consideration, as amended, is not anticipated by and could not have been obvious over Touitou et al., alone or in any combination with the cited references.

Rejection of Claims 1-9 under 35 USC 102 over US 6,328,992

The '992 Patent recites CBD as one of the components of marijuana and hashish and defines, "cannabis," as used in the specification, as including any of the components of cannabis. However, the specification actually provides no teaching of transdermal delivery of a composition consisting essentially of CBD. Putting aside what the '992 Patent actually teaches and reading the reference in the most favorable light only for purposes of this reply, the '992 Patent at best only teaches administration of mixtures of Delta8-THC, Delta9-THC and

Cannabinol and CBD. See, e.g., column 6, lines 25-34, where the specification teaches preparation of cannabis by extraction of oils from a cannabis plant. See, also, the Examples wherein the specification discloses only compositions comprising 3% Delta8-THC, 30% Delta9-THC, 35% CBD, and 32% Cannabinol.

In order to facilitate allowance of the pending claims, as amended, Applicants add that the subject matter of the claims under consideration, as amended, also was not obvious over the '992 Patent alone or in any combination with the cited references. As noted above, putting aside what the '992 Patent actually teaches and reading the reference in the most favorable light for purposes of this reply, the reference teaches administration of mixtures of cannabinoids.

Different compounds can have differing effects on transdermal delivery of other compounds. The mechanisms of transdermal delivery are not yet well enough understood to predict *a priori* what these effects will be. In some cases, a compound may enhance the movement of another compound through the skin; in other cases, it may impede such movement. In other cases, it may affect the pharmacological activity of another compound.

Because of possible chemical as well as physical and biological interactions between different pharmacologic agents, no one can predict with a reasonable degree of success how different compounds will behave when administered alone based on how they behave when administered in combination. Therefore, the subject matter of the claims under consideration, as amended, is not anticipated by and could not have been obvious over the '992 Patent, alone or in any combination with the cited references.

Rejection of Claim 11 under 35 USC 103(a) over US 6,328,992

Claim 11 has been canceled.

Rejection of Claim 10 under 35 USC 103(a) over Either of Touitou et al. or US 6,328,992 in view of US 20030158191

The '191 Application is cited as teaching addition of an opiate. However, as discussed above, Neither Touitou et al. or the '992 Patent teach transdermal delivery of a composition consisting essentially of CBD. This defect is not cured by the '191 Application and therefore the subject matter of claim 11 was not obvious over the cited references.

Rejection of Claim 10 under 35 USC 103(a) over Either of Touitou et al. or US 6,328,992 in view of Pugh et al.

Pugh et al. is cited as teaching addition of an opiate. However, as discussed above, neither Touitou et al. nor the '992 Patent teach transdermal delivery of a composition consisting essentially of CBD. This defect is not cured by Pugh et al. and therefore the subject matter of claim 11 was not obvious over the cited references.

In view of the above amendments and remarks, which are believed to be fully responsive to the objection and rejections set forth in the Office Action, Applicant respectfully requests reconsideration of the objection and rejections and respectfully requests prompt allowance of the claims under consideration, as amended. The Examiner is invited to contact Applicant's

undersigned attorney at the number provided below if such might facilitate allowance of the claims, as amended.

Respectfully submitted,



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Page 13 f 13